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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gary K. Michelson, M.D.

Serial No: N/A

Filed: June 13, 2000

For: MANUFACTURED MAJOR LONG BONE RING  
IMPLANT SHAPED TO CONFORM TO A PREPARED  
INTERVERTEBRAL IMPLANTATION SPACE

101.0078-00000  
09/593591  
06/13/00

Box PATENT APPLICATION

Assistant Commissioner for Patents

Washington, D.C. 20231

Dear Sir:

Transmitted herewith for filing is the patent application identified above.

- ☒ 3 sheet(s) of drawings (☐ formal ☒ informal) is(are) enclosed.
- ☒ 31 page(s) of specification and 1 page(s) of abstract of the invention are enclosed.
- ☐ An assignment of the invention to      ☐ is enclosed ☐ will follow.
- ☐ An associate power of attorney ☐ is enclosed ☐ will follow.
- ☐ A verified statement to establish small entity status under 37 C.F.R. §§ 1.9 & 1.27 is enclosed.
- ☒ Declaration and Power of Attorney ☒ is enclosed ☐ will follow.
- ☐ A certified copy of      Patent Application No.      filed      from which priority is claimed under 35 U.S.C. § 119 is enclosed.
- ☒ IDS enclosed (☒ with references).
- ☐ Preliminary Amendment is enclosed.

CALCULATION OF FEES								
ITEM		TOTAL NO. OF CLAIMS		NO. OF CLAIMS OVER BASE	LG/SM \$ ENTITY FEE		\$ AMOUNT	\$ FEE
A	TOTAL CLAIMS FEE	126	-20	106	LG=\$18 SM=\$9	\$18	\$1,908	
B	INDEPENDENT CLAIMS FEE*	3	-3	0	LG=\$78 SM=\$39	\$78	\$ 0	
C	SUBTOTAL - ADDITIONAL CLAIMS FEE (ADD FINAL COLUMN IN LINES A + B)							\$ 1,908
D	MULTIPLE-DEPENDENT CLAIMS FEE				LARGE ENTITY FEE = \$260 SMALL ENTITY FEE = \$130		\$ 0	
E	BASIC FEE				LARGE ENTITY FEE = \$690 SMALL ENTITY FEE = \$345		\$ 690	
F	TOTAL FILING FEE (ADD TOTALS FOR LINES C, D, AND E)							\$ 2,598
G	ASSIGNMENT RECORDING FEE						\$ 40	\$ 0
	*LIST INDEPENDENT CLAIMS [LIST OF INDEPENDENT CLAIMS]							

- ☒ A check in the amount of \$ 2,598 to cover the filing fee and extra claims fees is enclosed.
- ☐ A check in the amount of \$      to cover Assignment Recordation fee is enclosed.



06-14-00

A

PATENT

Attorney Docket No: 101.0078-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gary K. Michelson, M.D.

Serial No: N/A

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For: MANUFACTURED MAJOR LONG  
BONE RING IMPLANT SHAPED TO  
CONFORM TO A PREPARED  
INTERVERTEBRAL IMPLANTATION  
SPACE

Art Unit: N/A

Examiner: N/A

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Date of Deposit: June 13, 2000

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Assistant Commissioner for Patents  
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Dear Sir:

I hereby certify that

- ☒ Two copies of a letter of transmittal
- ☒ Check in amount of \$ 2,598.00 as filing fee and extra claims fees
- ☒ Patent application ( 31 page(s) of specification; 126 claim(s); 1 page(s) of abstract
- ☒ 3 sheet(s) of informal drawings
- ☒ Executed Declaration and Power of Attorney
- ☒ Information Disclosure Statement, PTO Form 1449, and copies of references
- ☒ Return postcard

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service with sufficient postage under 37 C.F.R. § 1.10 on the date indicated above and are addressed to:

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Washington, D.C. 20231

Date: June 13, 2000

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U.S. PATENT APPLICATION

IN THE NAME OF

Gary K. Michelson, M.D.

FOR A

MANUFACTURED MAJOR LONG BONE RING IMPLANT SHAPED TO CONFORM  
TO A PREPARED INTERVERTEBRAL IMPLANTATION SPACE

Prepared by:

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# MANUFACTURED MAJOR LONG BONE RING IMPLANT SHAPED TO CONFORM TO A PREPARED INTERVERTEBRAL IMPLANTATION SPACE

## BACKGROUND OF THE INVENTION

The diaphysis is the shaft of a long bone, as distinguished from the epiphysis, the end of the bone forming the joints. When the diaphysis is cut twice, more or less transversely, a complete bone ring is formed with the medulary canal forming an opening through the ring. Such rings are generally harvested from femurs for use in the lumbar spine. Other bones from the arm or leg or other part of the skeleton may be useful in various regions of the spine.

The use of diaphyseal bone rings, such as those harvested from human femurs, is well known in the art of spinal fusion. For interbody spinal fusion, femoral rings are formed by making two spaced apart cuts approximately perpendicular to the long axis of the diaphyseal portion of a human cadaveric femur. The cuts are generally spaced apart so as to form a ring having a height corresponding to the restored disc space or slightly greater. Femoral ring bone grafts are placed into the spine within and across the height of the space previously occupied by a spinal disc between adjacent vertebral bodies to achieve interbody fusion of those vertebral bodies through the disc space. The femoral ring bone graft is incorporated into the bony fusion over time.

Interbody spinal fusion with bone rings, however, has had limited success in the past. While all the causes for failure may not yet be appreciated, it is nevertheless believed that a failure to gain congruity at the interfaces of the bone ring implant to the adjacent vertebral bodies, and a failure to achieve stability of the bone ring implant, may

be two of the more significant factors subject to the surgeon's control contributing to such failures.

Bone rings that are entirely or almost entirely made of cortical bone offer the advantages of that material including an appropriate modulus of elasticity and strength for the prescribed use, the capacity to be bioactive, including being osteoconductive, osteoinductive, osteogenic, and to more generally provide a good substrate for the formation of new bone as fusion occurs. Further, by being bioabsorbable the bone material is replaced by the patient's own bone over time, thereby preventing stress shielding and leading to the eventual elimination of any foreign body from the implantation site.

As it is desirable to take advantage of all these benefits, there exists a need for an improved bone ring implant, which when used in accordance with the prescribed method of disc space preparation, provides for an improved congruity of the implant to the vertebral bodies and improved implant stability.

### SUMMARY OF THE INVENTION

The present invention is directed to a major long bone ring implant preferably, but not necessarily, an implant formed from a diaphyseal ring for insertion into an implantation space formed across a spinal disc between two adjacent vertebral bodies of the spine. The bone ring implant is preferably used in an implantation space having a wall portion, lip, or ridge with a flat portion for abutting the leading end of the bone ring implant. Such an implantation space can be formed with the instrumentation and method set forth in applicant's U.S. application serial no. 08/688,758, titled "Milling Instrumentation and Method for Preparing a Space Between Adjacent Vertebral

Bodies", incorporated by reference herein. It is appreciated however, that the bone ring implant of the present invention can be useful in implantation spaces formed by other techniques, such as for example, applicant's U.S. application serial no. 09/490,901, titled "Instrument And Method For Creating An Intervertebral Space For Receiving An Implant", incorporated by reference herein.

The bone ring implant is manufactured and machined to have a leading end and a trailing end opposite the leading end connected by opposed sides or walls. In combination the leading end, trailing end, and the opposed sides or walls preferably form one continuous perimeter having opposed upper and lower vertebral body engaging surfaces. By way of example and not limitation, while diaphyseal rings as harvested are generally round or oval, the bone ring implants of the present invention have a substantial flat portion at the leading end formed by cutting or machining the perimeter of the bone to create a straight cut portion at the leading end. The straight cut portion is generally oriented at 90° to the mid-longitudinal axis of the bone ring implant as defined by a line passing through the center of the bone ring implant from its leading end to its trailing end.

In a preferred embodiment, the bone ring implant is further machined so that one and preferably both of the opposed sides have portions that are straight and at a 90° angle to the straight cut portion of the leading end to produce straight portions that are outwardly facing. These straight portions are generally oriented parallel to the implant's longitudinal axis. The opposed sides may be machined to be generally parallel to each other over at least a portion of the sides and may be aligned or offset from each other along the implant sides. The present invention consists of the unique machined

structures of the bone ring implant, as well as may be used in combination with lockable screws, and preferably screw locks each preferably made of cortical bone or of a bioresorbable material.

The bone ring implant of the present invention may be machined so as to be adapted to receive through its trailing end at least a pair of opposed appropriately sized bone screws preferably, but not necessarily, made of cortical bone. The bone engaging screws may be aligned or offset from each other. At least one screw engages each of the vertebral bodies adjacent a disc space to be fused and into which the bone ring implant is implanted.

The bone ring implant of the present invention is preferably further machined and adapted to receive locks, preferably made of cortical bone, at the trailing end for securing the bone engaging screws therein and preventing the screws from backing out. The bone ring implant, bone screws, and/or locks can be made of a bioresorbable material, including but not limited to cortical bone, plastics and composite plastics. Suitable plastics may include those comprising lactides, galactides, glycolide, caprolactone, trimethylene carbonate, or dioxanone in various polymers, and/or combinations thereof.

The bone ring implant of the present invention can be further machined to have a specialized bone engaging surface configuration designed to enhance stability and resist motion imparted to each of the opposed upper and lower vertebrae engaging surfaces of the bone ring implant, such as for example the surface described in applicant's U.S. application serial no. 09/457,228 titled "Spinal Implant Surface Configuration" incorporated by reference herein.

The bone ring implant of the present invention is preferably for anterior implantation into the disc space and is preferably taller at the trailing end than at the leading end (the leading end being adapted to introduce the implant into the spine) so as to provide for a desired amount of lordosis.

The bone ring implant has been described as diaphyseal rings by way of example of one embodiment of the present invention. It should be clearly understood that such rings may be formed of bone that may be at least in part metaphyseal if sufficiently strong for the intended purpose. Alternatively, the bone ring implants may be made of a manufactured bone composite comprising of particles or filaments of bone and a bioresorbable plastic or ceramic or other suitable material without departing from the inventive concepts of the present invention, prime of which is a manufactured implant comprising cortical bone with a flat leading portion and preferably at least partial side portions that are flat and preferably 90° to the front of the implant.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top plan view of a vertebral body with preferably a machined implantation socket created therein for receiving a bone ring implant in accordance with the present invention.

FIG. 2A is a top plan view of a vertebral body showing the desired implantation socket with a first bone ring implant with a bone-engaging surface formed thereon and showing the machining of the bone ring required to obtain that ring's best fit to the recipient site (socket) within that vertebral body.

FIG. 2B is a top plan view of a vertebral body showing the desired implantation socket with a second bone ring implant with the bone-engaging surface formed thereon

and showing the machining of the bone ring required to obtain that ring's best fit to the recipient site (socket) within that vertebral body.

FIG. 3A is an enlarged fragmentary view along line 3—3 of FIG. 2A of the bone-engaging surface.

FIG. 3B is a side view of FIG. 3A illustrating the configuration of the bone-engaging surface.

FIG. 4 is a trailing end view of a bone ring implant in accordance with an embodiment of the present invention having openings oriented toward the adjacent vertebral bodies for receiving bone-engaging screws.

FIG. 5 is a side elevation view of the bone ring implant of FIG. 4.

FIG. 6 is a leading end view of the bone ring implant of FIG. 4.

FIG. 7 is a trailing end view of a bone ring implant in accordance with a second embodiment of the present invention.

FIG. 8 is a trailing end view of a bone ring implant in accordance with a third embodiment of the present invention.

FIG. 9 is a side elevation view of the bone ring implant of FIG. 6 with two bone engaging screws installed.

FIG. 10 is a top plan view of the bone ring implant of FIG. 6 machined to have a top exit screw hole and a bottom exit screw hole shown in hidden line.

#### OBJECTS OF THE PRESENT INVENTION

It is an object of an embodiment of the present invention to provide a manufactured bone ring implant having an improved contour and conformation with critical known dimensions.

It is a further object of an embodiment of the present invention to have the bone ring implant configuration conform, where critical, to an easily and reliably producible shape of an interbody recipient site.

It is a further object of an embodiment of the present invention to have opposed upper and lower vertebral body engaging surfaces configured to enhance the stability of the bone ring implant relative to the adjacent vertebral bodies when in use.

In a preferred embodiment of the present invention, it is a further object of the present invention to provide for an improved cortical bone ring implant adapted to receive at least a pair of opposed vertebral body engaging bone screws for further stabilizing the bone ring implant, and for stabilizing the adjacent vertebrae relative to the bone ring implant and to each other.

It is a further object of an embodiment of the present invention to provide for an interbody spinal fusion implant in the form of an improved ring of diaphyseal bone from a human long bone correspondingly dimensioned for a recipient site across the height of a disc space and in contact with each of the vertebral bodies adjacent that disc space.

It is a further object of an embodiment of the present invention to provide for an improved bone ring implant adapted to receive screw locks for locking opposed vertebral body engaging bone screws to the bone ring implant to prevent them from backing out.

#### DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a top plan view of a vertebral body V with an implantation space 20 created therein for receiving an implant. Implantation socket or space 20 has a

posterior wall 22 and side walls 24, 26 formed at least in part in the endplate of vertebral body V. By way of example and not limitation, implantation space 20 may be created with the apparatus and methods disclosed in applicant's U.S. application serial no. 08/688,758.

FIGs. 2A and 2B show top plan views of vertebral body V and first and second bone ring implants 30 and 40, respectively, placed thereon with the area of implantation space 20 identified by dotted lines. Bone rings can be made from a long bone of the human body, and preferably made from a human femur. First and second bone ring implants 30, 40 have outer perimeters that are intact and not modified from their naturally occurring state such as in a human femur. Bone ring implants 30, 40 in their natural state do not fit properly within the prepared implantation space 20 bordered by posterior wall 22 and side walls 24, 26 illustrated by the dotted lines. Bone ring implant 30 has sides that extend beyond side walls 24, 26 and a leading end 32 that extends beyond posterior wall 22 of implantation space 20 and protrudes from the posterior aspect of vertebral body V. Similarly, while bone ring implant 40 does not protrude from the posterior aspect of vertebral body V, leading end 42 extends beyond posterior wall 22 and has sides that extend beyond side walls 24, 26 of implantation space 20.

FIG. 3A shows an enlarged fragmentary view of a bone-engaging surface 50 that can be formed on bone ring implants described herein to increase the stability of the bone ring implants installed between two adjacent vertebral bodies. FIG. 3B is a side view of FIG. 3A illustrating the configuration of a preferred embodiment of bone-engaging surface 50. Bone engaging surface 50 has a forward facet 52 facing the leading end of the bone ring implant, an opposite rearward portion 54 facing the trailing

end of the bone ring implant, and opposed side facets 56, 58 directed generally toward the sides of the bone ring implant. Bone engaging surface 50 preferably facilitates motion in the direction of insertion and preferably resists motion in all other directions, including the direction opposite to the direction of insertion. While the specialized bone-engaging surface 50 is preferred, in the alternative the surfaces of the bone ring can be roughened, ratcheted, knurled, or otherwise modified when it is desired to increase the resistance of the bone ring implant to motion.

FIGs. 4-10 show a bone ring implant 100 in accordance with various preferred embodiments of the present invention. Bone ring implant 100 has a leading end 102 for insertion into the implantation space, an opposite trailing end 104, opposed upper and lower surfaces 106, 108, and opposed sides, 110, 112 therebetween. Upper and lower surfaces 106, 108 include a medulary canal 114 passing therethrough which may be useful to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through the medulary canal 114 in bone ring implant 100, which can to that end be filled with fusion promoting substances. Upper and lower surfaces 106, 108 may also be porous or include a bone ingrowth surface.

In a preferred embodiment of the present invention, leading end 102 and opposed sides 110, 112 are machined to configure bone ring implant 100 to conform to the shape of prepared implantation space 20. Leading end 102 and sides 110, 112 can be machined to have a more planar configuration to abut posterior wall 22 and side walls 24, 26, respectively, of implantation space 20. In this embodiment, the machined surfaces of leading end 102 and opposed sides 110, 112 are separated by the natural contour of the bone ring. For example, in a preferred embodiment, the bone ring

implant 100 can be machined so either or both of sides 110, 112 are at a 90° angle to the straight cut portion of leading end 102 to produce straight portions outwardly facing and generally parallel to each other, that can be aligned or offset from each other along sides 110, 112.

Alternatively, in another embodiment of the present invention, instead of being machined from a single bone, the bone ring implant can be manufactured from a composite of cortical fibers, filaments, particles, and a material which may or may not be bioactive and/or bioresorbable such as a plastic, ceramic, for example. Once formed, the composite implant material may be machined or molded, into the desired shape.

As shown in FIGs. 4, 9, and 10, in a preferred embodiment of the present invention, trailing end 104 can be machined to include openings 120, 122 for receiving bone-engaging screws 130, 132. Openings 120, 122 extend from trailing end 104 through upper and lower surfaces 106, 108, respectively, and are preferably oriented or directed toward the adjacent vertebral bodies. As shown in FIGs. 7 and 8, instead of openings 120, 122, trailing end 104 can include openings 132, 134, 136, 138, for receiving bone-engaging screws. Openings 132, 134, 136, 138 can be oriented toward upper and lower surfaces 106, 108 in an alternating manner as shown in FIG. 7. Alternatively, openings 132, 138 can be oriented toward upper surface 106 and openings 134, 136 can be oriented toward lower surface 108 as shown in Figure 8, or any combination thereof. The number of openings in trailing end 104 can vary depending on the size of the implant and the number of screws desired to be utilized by the surgeon.

In a further embodiment of the present invention, the medulary canal 114 of bone ring implant 100 may be loaded with fusion promoting substances and/or the implant may be treated with fusion promoting substances. Such substances may include, but are not limited to, bone morphogenetic protein (BMP), genetic material coding for the production of bone, mineralizing proteins, bone or bone products, and other materials.

In a further embodiment of the present invention, the medulary canal 114, which may or may not be machined, is compressively loaded with what is at least in part fusion promoting substances to increase the density of the filled area. Potentially, this allows for an increase in the quantities of fusion promoting material and provides the ability of the filled area to bear load.

The bone ring implants, bone screws, or locks could include a bioresorbable material including, but not limited to cortical bone, plastics and composite plastics. Suitable plastics may include those comprising lactides, galactides, glycolide, capronlactone, trimethylene carbonate, dioxanone in various polymers and/or combinations.

The present invention has been described as being an improved ring of bone harvested from the diaphyseal region of a long bone. This has been done to emphasize that the implant should have a substantial ring or perimeter of cortical bone. It is not necessary that the perimeter of cortical bone be uninterrupted or complete. The perimeter of the bone ring implant may include an open portion adapted to provide access to the medulary canal 114. Further, the implant could rely on some portion of denser cancellous bone and still conform to the teachings of the present invention. The present invention can include bone harvested from the area of the

Parameter	Value	Unit
Initial concentration	1.0	g/L
Initial pH	7.0	
Temperature	25	°C
Time	0-120	min
Agitation speed	150	rpm
Batch size	100	mL
Adsorbent dose	0.1-1.0	g/L
Adsorbent type	Activated carbon	
Adsorbent surface area	1000	m <sup>2</sup> /g
Adsorbent pore volume	0.5	cm <sup>3</sup> /g
Adsorbent density	1.5	g/cm <sup>3</sup>
Adsorbent particle size	0.15-0.25	mm
Adsorbent batch	1	
Adsorbent storage	Room temperature	
Adsorbent treatment	None	
Adsorbent regeneration	None	
Adsorbent disposal	Landfill	
Adsorbent reuse	None	
Adsorbent cost	1.0	\$/kg
Adsorbent availability	High	
Adsorbent stability	High	
Adsorbent toxicity	Low	
Adsorbent biodegradability	Low	
Adsorbent flammability	Low	
Adsorbent corrosivity	Low	
Adsorbent reactivity	Low	
Adsorbent compatibility	High	
Adsorbent safety	High	
Adsorbent handling	Easy	
Adsorbent storage	Easy	
Adsorbent transport	Easy	
Adsorbent disposal	Easy	
Adsorbent reuse	Easy	
Adsorbent regeneration	Easy	
Adsorbent treatment	Easy	
Adsorbent batch	1	
Adsorbent storage	Room temperature	
Adsorbent treatment	None	
Adsorbent regeneration	None	
Adsorbent disposal	Landfill	
Adsorbent reuse	None	
Adsorbent cost	1.0	\$/kg
Adsorbent availability	High	
Adsorbent stability	High	
Adsorbent toxicity	Low	
Adsorbent biodegradability	Low	
Adsorbent flammability	Low	
Adsorbent corrosivity	Low	
Adsorbent reactivity	Low	
Adsorbent compatibility	High	
Adsorbent safety	High	
Adsorbent handling	Easy	
Adsorbent storage	Easy	
Adsorbent transport	Easy	
Adsorbent disposal	Easy	
Adsorbent reuse	Easy	
Adsorbent regeneration	Easy	
Adsorbent treatment	Easy	

Parameter	Value	Unit
Initial concentration	1.0	g/L
Initial pH	7.0	
Temperature	25	°C
Time	0-120	min
Agitation speed	150	rpm
Batch size	100	mL
Adsorbent dose	0.1-1.0	g/L
Adsorbent type	Activated carbon	
Adsorbent surface area	1000	m <sup>2</sup> /g
Adsorbent pore volume	0.5	cm <sup>3</sup> /g
Adsorbent density	1.5	g/cm <sup>3</sup>
Adsorbent particle size	0.15-0.25	mm
Adsorbent batch	1	
Adsorbent storage	Room temperature	
Adsorbent treatment	None	
Adsorbent regeneration	None	
Adsorbent disposal	Landfill	
Adsorbent reuse	None	
Adsorbent cost	1.0	\$/kg
Adsorbent availability	High	
Adsorbent stability	High	
Adsorbent toxicity	Low	
Adsorbent biodegradability	Low	
Adsorbent flammability	Low	
Adsorbent corrosivity	Low	
Adsorbent reactivity	Low	
Adsorbent compatibility	High	
Adsorbent safety	High	
Adsorbent handling	Easy	
Adsorbent storage	Easy	
Adsorbent transport	Easy	
Adsorbent disposal	Easy	
Adsorbent reuse	Easy	
Adsorbent regeneration	Easy	
Adsorbent treatment	Easy	
Adsorbent batch	1	
Adsorbent storage	Room temperature	
Adsorbent treatment	None	
Adsorbent regeneration	None	
Adsorbent disposal	Landfill	
Adsorbent reuse	None	
Adsorbent cost	1.0	\$/kg
Adsorbent availability	High	
Adsorbent stability	High	
Adsorbent toxicity	Low	
Adsorbent biodegradability	Low	
Adsorbent flammability	Low	
Adsorbent corrosivity	Low	
Adsorbent reactivity	Low	
Adsorbent compatibility	High	
Adsorbent safety	High	
Adsorbent handling	Easy	
Adsorbent storage	Easy	
Adsorbent transport	Easy	
Adsorbent disposal	Easy	
Adsorbent reuse	Easy	
Adsorbent regeneration	Easy	
Adsorbent treatment	Easy	

What is claimed is:

1. An interbody spinal implant made of cortical bone for insertion at least in part into an implantation space formed across a disc space between adjacent vertebral bodies of a human spine and into at least a portion of the endplates of the vertebral bodies, the implantation space having a front wall, said implant comprising:

a body manufactured from a bone ring obtained from a major long bone of a human, said body having a perimeter, a leading end for insertion first into the disc space, a trailing end opposite said leading end, and opposite sides, said body having a length along a mid-longitudinal axis of said implant, said leading end having a generally straight portion along a portion of the perimeter of said body adapted to abut the front wall of the implantation space when said implant is installed into the implantation space;

opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies, said upper and lower surfaces being non-arcuate;

said opposite sides connecting said upper and lower surfaces and said leading and trailing ends; and

an opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant.

2. The implant of claim 1, wherein said straight portion of said leading end is generally oriented at 90 degrees to the mid-longitudinal axis of the implant.

3. The implant of claim 1, wherein at least one of said sides includes a straight portion.

4. The implant of claim 3, wherein said straight portion of said at least one side is generally oriented 90 degrees to said straight portion of said leading end.

5. The implant of claim 3, wherein said straight portion of said at least one side is oriented generally parallel to the mid-longitudinal axis of said implant.

6. The implant of claim 1, wherein said sides of said implant have straight portions that are generally parallel to each other.

7. The implant of claim 1, further comprising at least one protrusion extending from at least one of said upper and lower surfaces for engaging at least one of the adjacent vertebral bodies to maintain said implant within the implantation space.

8. The implant of claim 7, wherein said protrusion comprises at least one of a ridge, ratcheting, spline, and knurling.

9. The implant of claim 1, wherein said upper and lower surfaces are porous.

10. The implant of claim 1, wherein said upper and lower surfaces include a bone ingrowth surface.

11. The implant of claim 1, wherein the perimeter of said body forms at least a portion of a ring.
12. The implant of claim 1, wherein said implant has a closed perimeter.
13. The implant of claim 1, wherein said implant has an open perimeter for providing access to said opening.
14. The implant of claim 1, wherein said implant is generally rectangular in shape.
15. The implant of claim 1, wherein said implant is generally oval in shape.
16. The implant of claim 1, wherein at least a portion of said upper and lower surfaces are in an angular relationship to each other from trailing end to leading end for allowing angulation of the adjacent vertebral bodies relative to each other.
17. The implant of claim 1, wherein at least a portion of said leading end is tapered for facilitating insertion of said implant between the two adjacent vertebral bodies.
18. The implant of claim 1, wherein said implant is adapted for insertion from the anterior aspect of the vertebral bodies and said trailing end is configured to conform to the anatomic contour of at least a portion of the anterior aspect of the vertebral bodies.



26. The implant of claim 1, wherein said trailing end is adapted to receive at least one bone screw adapted to engage at least one vertebral body when inserted through said implant.

27. The implant of claim 26, further comprising a lock for locking at least one bone screw to said implant.

28. The implant of claim 27, wherein said lock is made of one of cortical bone and a bioresorbable material.

29. The implant of claim 28, wherein said screw is made of one of cortical bone and a bioresorbable material.

30. The implant of claim 1, wherein said implant is manufactured from one of a diaphyseal bone and from a metaphyseal bone.

31. The implant of claim 1, wherein said implant further comprises a bone composite material.

32. The implant of claim 1, further in combination with fusion promoting substances.

33. The implant of claim 1, in combination with a fusion promoting material other than bone.

34. The implant of claim 1, wherein said implant comprises a bone ingrowth material other than bone.

35. The implant of claim 1, further comprising a material, other than the bone from which said implant is formed, that intrinsically participates in the growth of bone from one of the adjacent vertebral bodies to the other of the adjacent vertebral bodies.

36. The implant of claim 1, wherein said fusion promoting substance is bone morphogenetic protein.

37. The implant of claim 1, further in combination with bone morphogenetic protein.

38. The implant of claim 1, further in combination with an osteogenic material.

39. The implant of claim 38, wherein said osteogenic material is a material other than bone.

40. The implant of claim 38, wherein said material is genetic material coding for the production of bone.

41. The implant of claim 1, further in combination with genetic material coding for production of bone.

42. The implant of claim 1, further in combination with a chemical substance to inhibit scar formation.

43. An interbody spinal implant made of a bone composite material for insertion at least in part into an implantation space formed across a disc space between adjacent vertebral bodies of a human spine and into at least a portion of the endplates of the vertebral bodies, the implantation space having a front wall, said implant comprising:

a body manufactured from a bone composite material, said body having a perimeter, a leading end for insertion first into the disc space, a trailing end opposite said leading end, and opposite sides, said body having a length along a mid-longitudinal axis of said implant, said leading end having a generally straight portion along a portion of the perimeter of said body adapted to abut the front wall of the implantation space when said implant is installed into the implantation space;

opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies, said upper and lower surfaces being non-arcuate;

said opposite sides connecting said upper and lower surfaces and said leading and trailing ends; and

an opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant.

45. The implant of claim 43, wherein at least one of said sides includes a straight portion.

46. The implant of claim 45, wherein said straight portion of said at least one side is generally oriented 90 degrees to said straight portion of said leading end.

47. The implant of claim 45, wherein said straight portion of said at least one side is oriented generally parallel to the mid-longitudinal axis of said implant.

48. The implant of claim 43, wherein said sides of said implant have straight portions that are generally parallel to each other.

49. The implant of claim 43, further comprising at least one protrusion extending from at least one of said upper and lower surfaces for engaging at least one of the adjacent vertebral bodies to maintain said implant within the implantation space.

50. The implant of claim 49, wherein said protrusion comprises at least one of a ridge, ratcheting, spline, and knurling.

51. The implant of claim 43, wherein said upper and lower surfaces are porous.

52. The implant of claim 43, wherein said upper and lower surfaces include a bone ingrowth surface.

53. The implant of claim 43, wherein the perimeter of said body forms at least a portion of a ring.

54. The implant of claim 43, wherein said implant has a closed perimeter.

55. The implant of claim 43, wherein said implant has an open perimeter for providing access to said opening.

56. The implant of claim 43, wherein said implant is generally rectangular in shape.

57. The implant of claim 43, wherein said implant is generally oval in shape.

58. The implant of claim 43, wherein at least a portion of said upper and lower surfaces are in an angular relationship to each other from trailing end to leading end for allowing angulation of the adjacent vertebral bodies relative to each other.

59. The implant of claim 43, wherein at least a portion of said leading end is tapered for facilitating insertion of said implant between the two adjacent vertebral bodies.

60. The implant of claim 43, wherein said implant is adapted for insertion from the anterior aspect of the vertebral bodies and said trailing end is configured to conform to the anatomic contour of at least a portion of the anterior aspect of the vertebral bodies.

61. The implant of claim 43, wherein said implant has a maximum length less than and approximating the posterior to anterior depth of the vertebral bodies.

62. The implant of claim 43, wherein said implant has a width greater than one half the width of the adjacent vertebral bodies.

63. The implant of claim 43, wherein said opening is compressively loaded with fusion promoting material.

64. The implant of claim 43, further comprising at least a second opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant.

65. The implant of claim 64, wherein said second opening communicates with said opening.

66. The implant of claim 43, further comprising a plurality of openings and passages adapted to retain a fusion promoting substance.

67. The implant of claim 43, wherein said trailing end is adapted to receive at least one bone screw adapted to engage at least one vertebral body when inserted through said implant.

68. The implant of claim 67, further comprising a lock for locking at least one bone screw to said implant.

69. The implant of claim 68, wherein said lock is made of one of cortical bone and a bioresorbable material.

70. The implant of claim 68, wherein said screw is made of one of cortical bone and a bioresorbable material.

71. The implant of claim 43, wherein said composite material includes filaments of bone.

72. The implant of claim 43, wherein said composite material includes a bioresorbable plastic.

73. The implant of claim 43, wherein said composite material includes ceramic.

74. The implant of claim 43, further in combination with fusion promoting substances.

75. The implant of claim 43, in combination with a fusion promoting material other than bone.

76. The implant of claim 43, wherein said implant comprises a bone ingrowth material other than bone.

77. The implant of claim 43, further comprising a material, other than the bone from which said implant is formed, that intrinsically participates in the growth of bone from one of the adjacent vertebral bodies to the other of the adjacent vertebral bodies.

78. The implant of claim 43, wherein said fusion promoting substance is bone morphogenetic protein.

79. The implant of claim 43, further in combination with bone morphogenetic protein.

80. The implant of claim 43, further in combination with an osteogenic material.

81. The implant of claim 80, wherein said osteogenic material is a material other than bone.

82. The implant of claim 81, wherein said material is genetic material coding for the production of bone.

83. The implant of claim 43, further in combination with genetic material coding for production of bone.

84. The implant of claim 43, in combination with a chemical substance to inhibit scar formation.

85. An interbody spinal implant made of cortical bone for insertion at least in part into an implantation space formed across a disc space between adjacent vertebral bodies of a human spine and into at least a portion of the endplates of the vertebral bodies, the implantation space having a front wall, said implant comprising:

a body manufactured from a bone ring obtained from a major long bone of a human, said body having a perimeter, a leading end for insertion first into the disc space, a trailing end opposite said leading end, and opposite sides therebetween, said body having a length along a mid-longitudinal axis of said implant, said leading end having a generally straight portion along a part of the perimeter of said body adapted to abut the front wall of the implantation space when said implant is installed into the implantation space;

opposite upper and lower surfaces adapted to be placed in contact with and to support the adjacent vertebral bodies, said upper and lower surfaces being non-arcuate;

said opposite sides connecting said upper and lower surfaces and said leading and trailing ends;

an opening passing through said upper and lower surfaces for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant; and

said implant being formed by the process of cutting a section of a long bone in a direction transverse to the longitudinal axis of the long bone to form at least a portion of a bone ring and machining said leading end to form said straight portion.

86. The implant of claim 85, wherein said straight portion of said leading end is generally oriented at 90 degrees to the mid-longitudinal axis of the implant.

87. The implant of claim 85, wherein at least one of said sides includes a straight portion.

88. The implant of claim 87, wherein said straight portion of said at least one side is generally oriented 90 degrees to said straight portion of said leading end.

89. The implant of claim 87, wherein said straight portion of said at least one side is oriented generally parallel to the mid-longitudinal axis of said implant.

90. The implant of claim 85, wherein said sides of said implant have straight portions that are generally parallel to each other.











Variable	Mean	SD	Min	Max
Age	34.5	10.2	22	55
Gender	0.5	0.5	0	1
Marital status	0.6	0.5	0	1
Education	12.5	1.5	10	15
Income	1500	500	1000	2500
Health status	0.8	0.2	0	1
Employment status	0.7	0.3	0	1
Family size	3.5	1.5	1	6
Home ownership	0.6	0.5	0	1
Vehicle ownership	0.4	0.5	0	1
Life satisfaction	4.5	1.5	1	7
Health satisfaction	5.5	1.5	1	7
Financial satisfaction	4.0	1.5	1	7
Relationship satisfaction	5.0	1.5	1	7
Community satisfaction	4.5	1.5	1	7
Environment satisfaction	4.0	1.5	1	7
Overall satisfaction	4.5	1.5	1	7

Variable	Mean	SD	Min	Max
Age	34.5	10.2	22	55
Gender	0.5	0.5	0	1
Marital status	0.6	0.5	0	1
Education	12.5	1.5	10	15
Income	1500	500	1000	2500
Health status	0.8	0.2	0	1
Employment status	0.7	0.3	0	1
Family size	3.5	1.5	1	6
Religious affiliation	0.4	0.4	0	1
Political affiliation	0.5	0.5	0	1
Home ownership	0.6	0.5	0	1
Vehicle ownership	0.7	0.4	0	1
Travel frequency	0.3	0.3	0	1
Shopping frequency	0.4	0.4	0	1
Eating frequency	0.5	0.5	0	1
Exercise frequency	0.2	0.2	0	1
Drinking frequency	0.1	0.1	0	1
Smoking frequency	0.05	0.05	0	1
Overall health score	75	15	50	100

FIG. 1

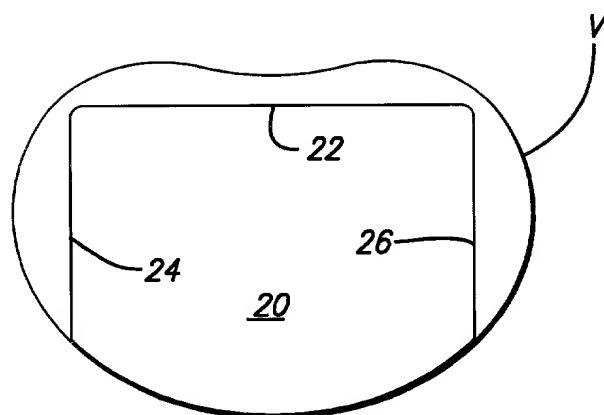


FIG. 2A

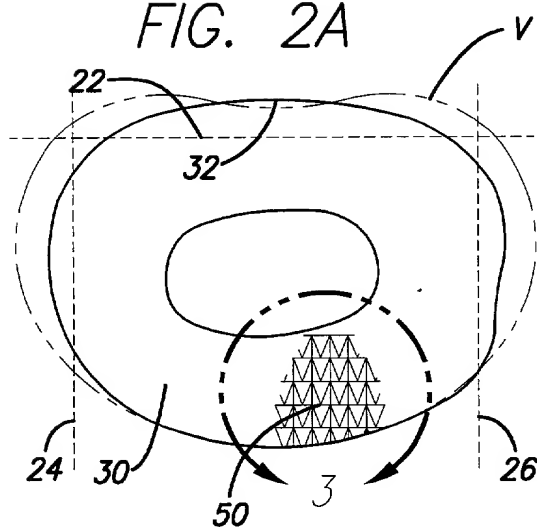


FIG. 2B

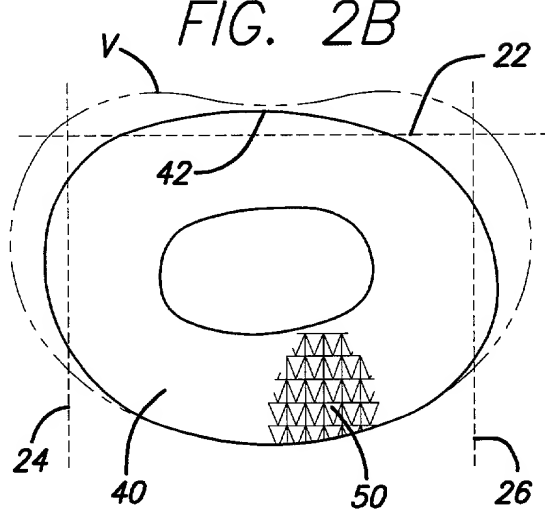


FIG. 3A

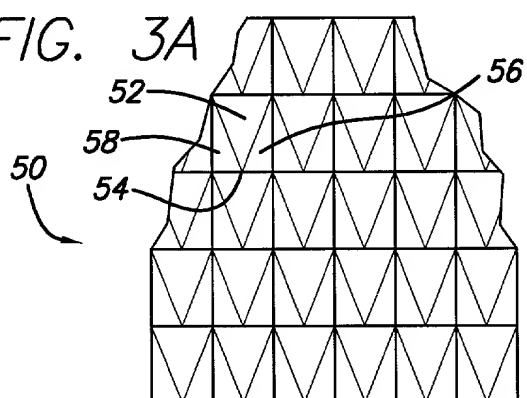
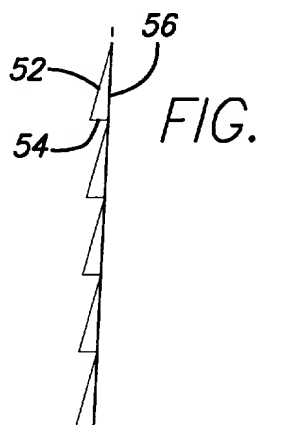
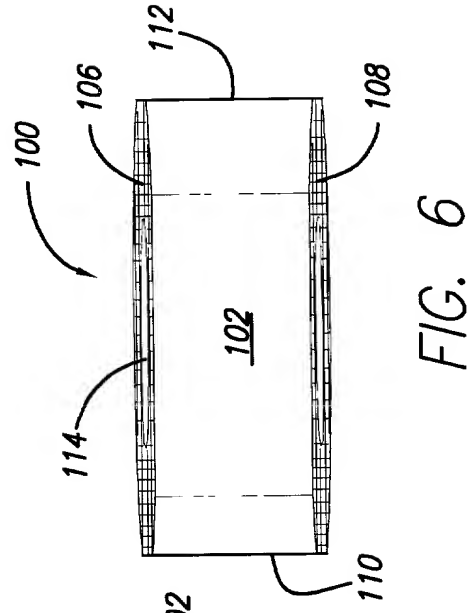
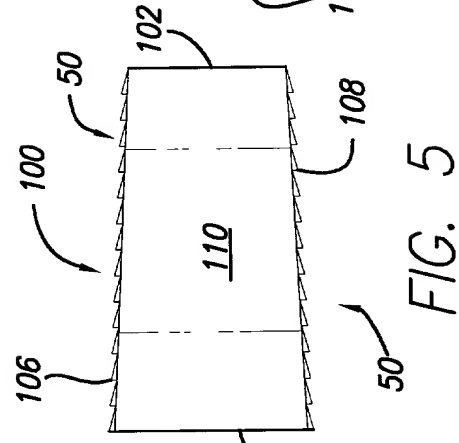
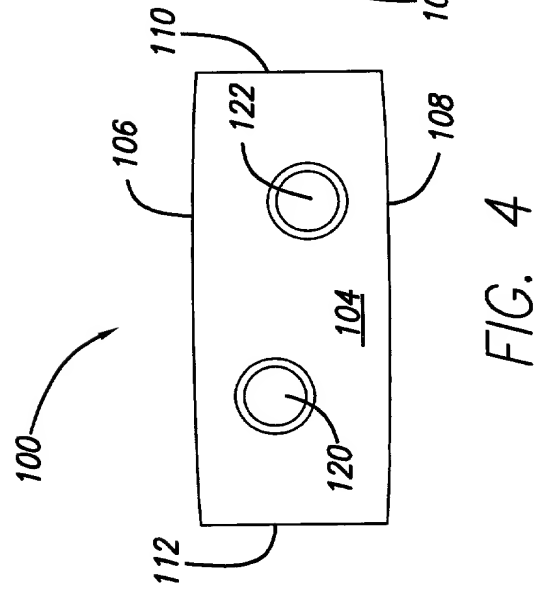
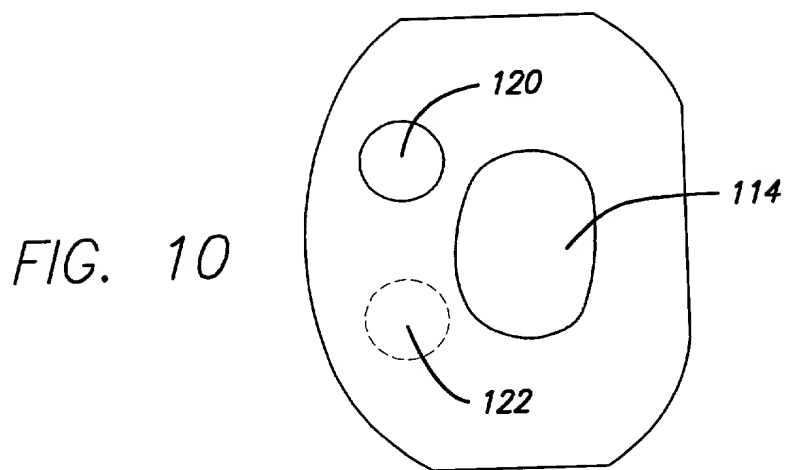
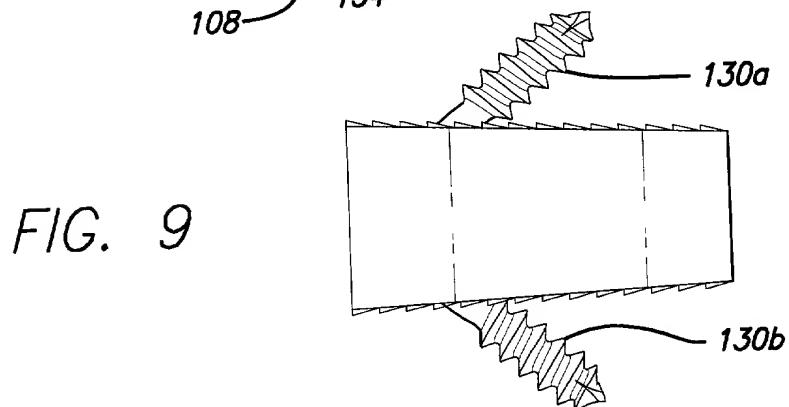
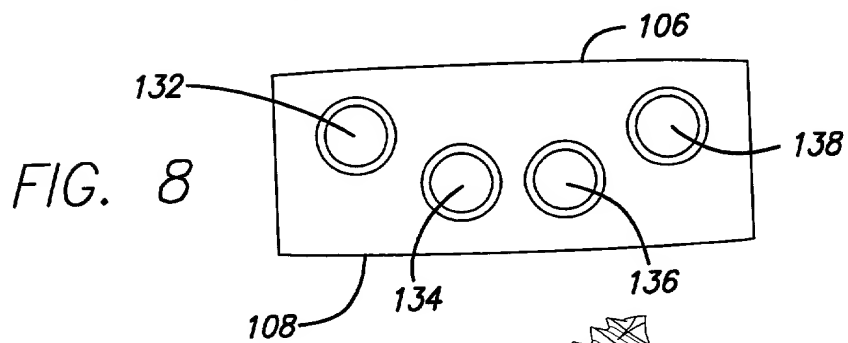
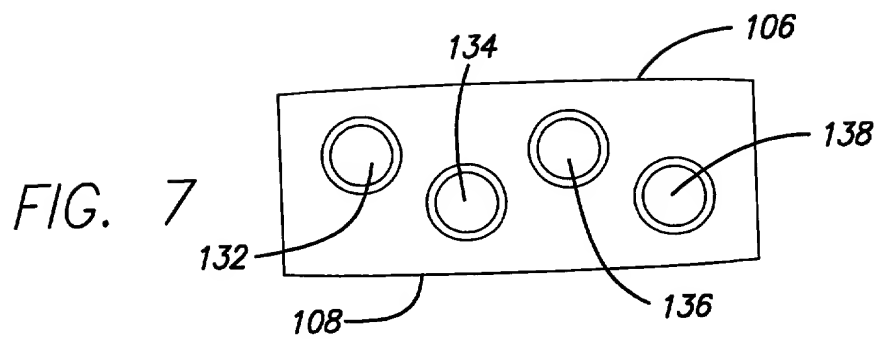


FIG. 3B







**DECLARATION  
and POWER OF ATTORNEY**

As a below named inventor, I declare that the information given herein is true, that I believe that I am the original, first and sole inventor (if only one name is listed as 1 below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**MANUFACTURED MAJOR LONG BONE RING IMPLANT SHAPED TO CONFORM TO A PREPARED INTERVERTEBRAL IMPLANTATION SPACE,**

the specification of which is attached hereto unless the following box is checked:

☐ was filed on \_\_\_\_ as United States Application Number or PCT International Application Number \_\_\_\_ and was amended on \_\_\_\_.

My residence, post office address and citizenship are as stated below next to my name.

I acknowledge my duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations § 1.56(a).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also

identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

**PRIOR FOREIGN APPLICATION(S)**

COUNTRY	APPLICATION NUMBER	DATE OF FILING Month Day Year	PRIORITY CLAIMED UNDER 35 U.S.C. 119
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I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

(Application Serial No.)

(Filing Date)

(Status)

**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following attorney(s) and/or Agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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	Post Office Address		CITIZENSHIP
3	Name of Inventor	Residence: CITY	STATE or COUNTRY
	Post Office Address		CITIZENSHIP
4	Name of Inventor	Residence: CITY	STATE or COUNTRY
	Post Office Address		CITIZENSHIP

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 1 	SIGNATURE OF INVENTOR 2
DATE <b>6/8/2000</b>	DATE
SIGNATURE OF INVENTOR 3	SIGNATURE OF INVENTOR 4
DATE	DATE